

REMARKS

The Office Action dated May 6, 2004, has been carefully considered. Claims 1-16 and 18-19 are pending in the present application. Claims 1, 18, and 19 have been amended to more particularly point out and distinctly claim the present method. No new matter has been introduced. Entry of the above amendments and reconsideration of the present application in view of the following remarks are respectfully requested.

I. DOUBLE PATENTING REJECTION

Claims 1-16 and 18-19 have been rejected under the judicially created doctrine of obviousness-type double patenting. Claims 1-16 and 18-19 have been rejected as allegedly being unpatentable over claims 1-16 of U.S. Patent No. 6,669,980.

While not agreeing with this rejection, attorneys for applicants submit herewith a Terminal Disclaimer Under 37 C.F.R. § 1.321(c) with respect to U.S. Patent No. 6,669,980 with the necessary fee to overcome the double patenting rejection. Common ownership of the present application and United States Patent No. 6,669,980 is established in the Terminal Disclaimer. Such Terminal Disclaimer is believed to obviate this rejection.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-10, 12, 15-16, and 18-19 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,355,058 B1 to Pacetti *et al.* ("Pacetti") in view of U.S. Patent No. 4,749,125 to Escallon *et al.* ("Escallon") and U.S. Patent No. 4,505,957 To Cobbs, Jr. *et al.* ("Cobbs"). This rejection is traversed.

Independent claims 1, 18, and 19 recite methods for coating at least a portion of a medical device, including *inter alia*, providing a medical device (claims 1 and 18) or an implantable stent (claim 19) that has a portion that has a surface adapted for exposure to body tissue of a patient, and applying to the surface a coating formulation comprising a polymeric material and a solvent by: (1) providing a nozzle apparatus comprising a chamber connected to at least one opening for dispensing the coating formulation; (2) placing the coating formulation into the chamber; (3) electrically charging the coating formulation; (4) creating droplets of the electrically charged coating formulation; and (5) depositing the droplets of coating formulation onto the grounded surface to form a coating on the surface. Claims 2-10, 12, and 15-16 depend from claim 1, and thus also include those limitations.

Pacetti does not disclose or suggest the presently claimed method for coating at least a portion of a medical device. As stated in the Office Action on page 3, Pacetti does not disclose or suggest the use of the recited nozzle apparatus. In particular, Pacetti does not disclose or suggest a coating method using a nozzle apparatus in which the coating formulation is first electrically charged before the coating formulation is formed into droplets that are electrically charged. As noted in the specification at pages 2-3, in the conventional electrostatic deposition coating methods, the droplets are first formed and then the droplets are electrically charged. Such conventional coating methods are typically used to coat various substrates and, in fact, have been used after the filing date of the present application. *See, e.g.,* U.S. Patent No. 6,780,475 to Fulton *et al.*, attached hereto as Appendix A.¹

Pacetti does not provide any indication that the electrostatic spraying method that it mentions is a method other than the conventional electrostatic spray coating method. Therefore, the mere disclosure in Pacetti that electrostatic liquid spraying can be used does not teach or suggest the present method, which, unlike conventional electrostatic spraying methods, first electrically charges the coating formulation and then forms droplets from such charged formulation.

To remedy the deficiencies of Pacetti, the Examiner relies on Escallon. However, Escallon does not disclose or suggest that its nozzle apparatus may be used in a method for coating at least a portion of a medical device, wherein the portion has a surface adapted for exposure to body tissue of a patient as recited in the present claims. In fact, Escallon does not even disclose or suggest a method for coating a medical device, and thus does not disclose or suggest the method of the present invention. Accordingly, Escallon does not disclose or suggest providing a medical device such as an implantable stent having a portion that has a surface adapted for exposure to body tissue of a patient as recited in the present claims.

In addition, Escallon does not even disclose or suggest applying to the surface of a medical device a coating formulation comprising a polymeric material and a solvent as

¹ U.S. Patent No. 6,780,475 was filed on May 28, 2002, which is after the September 18, 2001 filing date of U.S. Patent Application No. 09/95579, the parent application of the present application. U.S. Patent No. 6,780,475 discloses a method which includes forming particles and then electrostatically charging such particles on a substrate such as a medical device. Col. 1, lines 56-60; col. 6, lines 63-64.

presently claimed. Instead, Escallon teaches that its apparatus is used to apply, *inter alia*, pesticides to plants, adhesives to woods, and chemicals to food. (Col. 9, lines 36-41.)

Furthermore, there is no motivation in the teachings of Escallon to use the method of the present invention to apply a coating comprising a polymer and a solvent on a medical device, particularly where Escallon does not disclose or suggest applying a coating formulation comprising a polymer and a solvent to a medical device having a surface adapted for exposure to body tissue of a patient, as presently claimed. With respect to claim 19, Escallon also does not disclose or suggest applying a coating formulation that further includes a biologically active material to the surface of an implantable stent.

Therefore, there is also no motivation to combine Pacetti and Escallon. In particular, there is no teaching in Pacetti that an electrostatic spray-coating method in which a coating formulation is first electrically charged and then formed into droplets should be used to coat a medical device. Moreover, Escallon fails to provide any teaching or suggestion that its device should be used to coat medical devices. Thus, neither of these references provide a motivation to combine its teaching with those of the other. *B.F. Goodrich Company v. Aircraft Braking Systems Corporation*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Applicant's specification cannot be relied upon to provide such motivation. *See In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Accordingly, Pacetti cannot be combined with Escallon to arrive at the present invention.

Cobbs does not remedy the deficiencies of Pacetti and Escallon. Cobbs, like Escallon, does not disclose or suggest a method of coating a medical device. There is no teaching or suggestion that the methods and apparatus in Cobbs can be used to coat medical devices. Instead, Cobbs teaches that its coating methods and apparatus are used for applying paints and industrial coatings. (See, e.g., col. 4, lines 33-35, and col. 5, lines 44-62).

Moreover, although the Examiner states that Cobbs teaches that electrostatic liquid spray-coating techniques are employed for coating liquid materials, such as paints, it should be noted that Cobbs actually teaches away from using such electrostatic liquid spray-coating techniques. Specifically, in the "Background of the Invention" section, Cobbs does describe electrostatic liquid spray-coating techniques. However, Cobbs states that problems are associated with electrostatic liquid spray-coating methods because these methods involve large amounts of solvents that cause pollution problems. To overcome such pollution problems, large expenses must be incurred to dispose of solvents. (Col. 1, lines 27-50.) In

order to avoid these expenses, Cobbs claims he developed a coating method that, unlike electrostatic liquid spray-coating, uses minor amounts of volatile solvents. (Col. 3, lines, 9-23). Thus, Cobbs does not disclose or suggest the method of the present invention and instead teaches away from using an electrostatic spray coating method.

The Federal Circuit has stated that one cannot consider a reference in less than the entirety, *i.e.*, disregard disclosures in the reference that diverge from and teach away from the invention. Specifically, the Federal Circuit has stated, "It is impermissible within the framework of a Section 103 rejection to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what the reference fairly suggests to one of ordinary skill in the art". *In re Wesslau*, 353 F.2d 238, 241 (CPCA 1965). Moreover, the Federal Circuit has made very clear that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

For the above reasons, one of ordinary skill in the art would not be motivated to combine the teachings of Pacetti, Escallon, and Cobbs to obtain the present invention. Thus, it is believed that claims 1-10, 12, 15-16, and 18-19 are patentable over Pacetti, Escallon and Cobbs. Accordingly, withdrawal of this rejection and allowance of claims 1-10, 12, 15-16, and 18-19 are respectfully requested.

III. CONCLUSION

As the claim rejections have been overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Respectfully submitted,

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Enclosures